



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION®
Docket No. 97E-0292

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

ADD 13 1998

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,867,907 filed by Albemarle Corporation under 35 U.S.C. § 156. The patent claims the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION® (2,2'-ethylidenebis(4,6-di-tertbutylphenyl)fluorophosphonite), food additive petition FAP 1B4281.

In the August 4, 1998, issue of the Federal Register (63 Fed. Reg. 41580), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 1, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Teresa Stanek Rea
Burns, Doane, Swecker & Mathis, LLP
P.O. Box 1404
Alexandria, VA 22313-1404

97E-0292

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

501 Memorandum P1:31

Date: APR 13 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION®

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **97E-0292** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,867,907**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.